

June 19, 1985

Dear Home User Support Organization:

This is to alert you to a potential danger involving apnea monitors, and to ask that you notify your members of the need for certain precautions to prevent deaths and serious injuries to infants and children.

Three apnea monitor accidents have recently occurred in homes where these devices were being used. In one case, one end of the electric (power) cord was unplugged from the monitor while the other end was left unplugged into the wall socket. At the same time, the leads were disconnected from the monitor while the infant was still wearing the electrodes. An older sibling then plugged the loose ends of the lead into the "live" electric (power) cord (see illustration 1) causing the infant's electrocution. In the other two cases, young children plugged the loose ends of the leads in one instance into a wall socket and in the other instance into an electric (power) cord, causing burns.

We want to stress that these are unusual accidents in which the apnea monitors themselves did not malfunction. To prevent such accidents, apnea monitor users should:

- Never allow the electrode leads to remain attached to the infant unless they are also attached to the patient cable or apnea monitor.
- If the electric (power) cord is unplugged from the apnea monitor, be sure that the cord is also unplugged from the wall socket.
- Take steps to prevent young children from inserting any object into electric outlets.

We are working with apnea monitor manufacturers to develop a permanent solution to this problem. In the meantime, it is important that the steps listed above be taken to reduce the likelihood of such accidents.

If you have any questions please contact Dr. Lireka Joseph of the Food and Drug Administration (FDA) at 301-443-4600. Inquires from home users can be referred to Ms. Pam Chissler, also of the FDA, at 301-443-4190, Center for Devices and Radiological Health (HFZ-210), 5600 Fishers Lane, Rockville, Maryland 20857.

Sincerely yours,

John C. Villforth  
Director  
Center for Devices and  
Radiological Health

Enclosure: Illustrations